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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,758	05/11/2001	Takuya Watanabe	55862	1000

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EXAMINER

ULM, JOHN D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,758

Applicant(s)

Watanabe et al.

Examiner

John Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 3, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-44 is/are pending in the application.
- 4a) Of the above, claim(s) 8-19 and 22-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 20, and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1) Claims 1 to 6 and 8 to 44 are pending in the instant application. Claims 2 and 4 to 6 have been amended and claim 7 has been canceled as requested by Applicant in Paper Number 15, filed 03 March of 2003.

2) Claims 8 to 19 and 22 to 44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made in Paper No. 14, filed 03 March of 2003. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3) Claims 3 to 6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant's traversal of this objection ignores the premise upon which it was made. The test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends (35 U.S.C. 112, fourth paragraph) or in other words that it shall not conceivably be infringed by anything which would not also infringe the basic claim. Claim 3 can be infringed by a polypeptide consisting only of the amino acid sequence presented in residues 81 to 92 of SEQ ID NO:1. Such a polypeptide would not infringe claim 1, which requires the entire amino acid sequence presented in SEQ ID NO:1. Therefore, claim 3 can not properly depend from claim 1 because claim 3 can conceivably be

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infringed by something which would not also infringe claim 1. See 608.01(n)III. Correction is required,

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4) Claims 1 to 6 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims encompass a polypeptide as it occurs in nature.

5) Claims 1 to 6, 20 and 21 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding an alleged preproprotein comprising three putative RF-amide-like polypeptides, and the preproprotein encoded thereby. The instant application does not disclose a specific biological role or activity for any one of the three putative neuropeptides or their significance to a particular disease, disorder of physiological process which one would wish to manipulate for a desired clinical effect. Further, claim 3 encompasses any "partial peptide" of SEQ ID NO:1, which includes dipeptides, tripeptides, etc. for which the instant applications makes no assertion of a specific utility.

It is clear from the instant specification that the protein described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this

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protein or the putative neuropeptides contained therein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. Whereas one could readily employ a putative protein of the instant invention in an assay to identify agonist and antagonists to the putative neuropeptides contained therein the information obtained thereby would be of little use until one discovers the identity of those physiological processes mediated by those putative neuropeptides. Because the instant specification has failed to credibly identify a relevant physiological process which has been shown to be influenced by the administration of a putative neuropeptide of the instant invention, an artisan would have no way of predicting what effects the administration of that peptide to an organism would have. If one can not predict what effects that the administration of a putative neuropeptide of the instant invention is going to have on an organism then it is unclear as to what practical benefit is derived by the public from the identification of that peptide.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which

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requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a preproprotein containing three putative neuropeptides of as yet undetermined function or biological significance. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that a protein of the instant invention is associated in any way with the plurality of causally unrelated disorders that are listed on pages 64 to 77 and 93 to 11 of the instant specification, which appears to identify every disease, disorder, injury or physiological process known to be associated with humans. Until some actual and specific significance can be attributed to the claimed protein or the putative neuropeptides contained therein, the instant invention is incomplete. The putative neuropeptides of the instant invention are compounds that appear to be structurally analogous to peptides which are known in the art to function as neurotransmitters. In the absence of a knowledge of the natural roles or biological significance of these putative neuropeptides, there is no immediately obvious patentable use for them. To employ a protein of the instant invention in the identification of those physiological processes mediated by the putative neuropeptides contained therein is clearly to use

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it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the putative neuropeptides described therein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6) Claims 1 to 6, 21 and 22 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7) Claims 1 to 6, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 to 6, 20 and 21 are vague and indefinite because the metes and bounds of the limitations "substantially the same" and "consisting essentially of" are undeterminable when employed to define the structural elements of a chemical compound. The term "substantially the same" is vague because it is not possible to determine at what point in deviation a different but similar sequence would cease to be "substantially the same" as the reference sequence. The term "consisting essentially of" is routinely employed in patent practice

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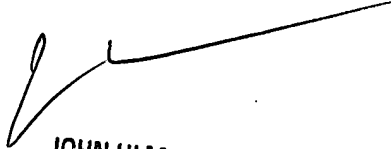
to identify the critical components in a "chemical composition". The purpose of employing this term in a composition claim is to indicate that the presence or absence of trace compounds in a composition which are not designated in a claim are not to be considered in determining if a composition is encompassed by that claim. The employment of this term in the designation of a structural element in a compound is improper because the structure of that compound can either "comprise" that element (open) or it can "have" that element (closed), but it can not "consist essentially of" a structural element.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800